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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,225	01/16/2004	Wolfgang Albrecht	NI 160	2196

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KLAUS J. BACH & ASSOCIATES  
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EXAMINER
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GODFREY, KEITH JOSEPH

ART UNIT	PAPER NUMBER
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1732

MAIL DATE	DELIVERY MODE
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09/07/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/762,225	<b>Applicant(s)</b> ALBRECHT ET AL.	
	<b>Examiner</b> Keith J. Godfrey	<b>Art Unit</b> 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Oath/Declaration***

Examiner has objected to the Oath/Declaration because of a typo in the PCT reference document PCT/DE02/02294, should be PCT/DE02/02249, emphasis added. Appropriate correction and new submission of Oath/Declaration with correct PCT/DE02/02249 is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 - 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. (have to reject all the claims which contain the indefinite limitation)

The term "in a manner known per se" in claim 1 renders the claim indefinite because it is not clear what methods are encompassed by the claim, thereby rendering the scope of the claim unclear.

With respect to claim 9, A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation

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given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 9 recites the broad recitation 10 to 90%, and the claim also recites 40 to 60% which is the narrower statement of the range/limitation.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Koros (US 5599380) with Brenner et al. (US 4973320) and Meyst el al. (US 4283289) cited to demonstrate an inherent state of fact.

**As to claim 1**, Koros (US 5599380) teaches a method of producing a polymeric membrane including: dissolving a first polymer(s) (preparing a first polymer) in a

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suitable solvent to form a core (blood compatible) solution (homogeneous solution) (col. 2, lines 56-61); dissolving a second polymer(s) (preparing a second polymer) in a suitable solvent to form a sheath (tissue compatible) solution (homogeneous solution) (col. 2, lines 62-63); coextruding the core (blood compatible) and sheath (tissue compatible) through a spinneret (contacting solutions) orifice (nozzle) to provide a multicomponent fiber membrane (layered polymer) (col. 2, lines 64-67); introducing the multicomponent fiber membrane into a coagulation bath to solidify the fiber (subject to phase inversion) (col. 3, lines 3-6); and extracting the solvent (non-membrane components freed) (col. 7, lines 1-4). Although Koros (US 5599380) does not expressly state the first and second polymers are blood compatible and tissue compatible, respectively, the references Meyst et al. (US 4283289) (col. 4, lines 28-30) and Brenner et al. (US 4973320) (col. 3, lines 9-12) specifically teach that the first and second polymers used in Koros (US 5599380) are blood compatible and tissue compatible, respectively.

**As to claim 2**, Koros (US 5599380) teaches an additional step in the process described above including drawing the multicomponent fiber membrane (layered polymer) through an air gap (col. 3, lines 1-2).

**As to claim 3**, Koros (US 5599380) teaches multicomponent hollow fiber membrane extruded through a spinneret (spin extrusion nozzle) (col. 3, lines 5-6 and col. 2, lines 64-67).

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**As to claim 4**, Koros (US 5599380) teaches extruding the polymer solutions through a multiple channel spinneret while maintaining a gas pressure in the hollow fiber (core) (col. 5, lines 49-54).

**As to claim 5**, Koros (US 5599380) discloses a bore fluid (lumen filler) to facilitate generation of the hollow fiber (col. 6, lines 33-44).

**As to claim 6**, Koros (US 5599380) teaches using a polyurethane outer layer (tissue compatible polymer) (col. 3, line 48) and a polyamide inner layer (blood compatible polymer) (col. 3, line 58). It is noted that Brenner et al. (US 4973320) specifically teaches that polyurethanes are tissue compatible (Brenner et al. (US 4973320) (col. 3, lines 9-12) and Meyst el al. (US 4283289) specifically teaches that polyamides are blood compatible (Meyst el al. (US 4283289) (col. 4, lines 28-30).

**As to claim 7**, Koros (US 5599380) teaches that a common solvent dimethyl formamide (DMF) can be used (col. 8, lines 5-13).

As each and every element of the claimed invention is taught in the prior art as recited above, the claims are anticipated by Koros (US 5599380).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Koros (US 5599380), as described above in claims 1-7 above.

The teachings of Koros are as described above for claims 1-7.

**As to claim 8**, Koros (US 5599380) does not expressly teach a specific additional polymer being common to both first and second polymers, however, Koros (US 5599380) states that the polymers used for the gas separation layer (tissue compatible layer) can be blended, substituted, or copolymers (col. 3, lines 47-50) and that the substrate layer (blood compatible layer) can be blended, copolymerized and substituted (col. 4, lines 1-2) suggesting that the two polymer layers can each be blended with an additional common polymer, such as polyamid, which is common to both layers as a choice for use (col. 3, line 31 and col. 3, line 59). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to blend a common polymer with the gas separation layer (tissue compatible layer) and substrate layer (blood compatible layer), as taught by Koros (US 5599380), because the an additional common polymer may increase layer compatibility.

**As to claim 9**, Koros (US 5599380) does not expressly teach a mass content of blood-compatible and tissue compatible polymers and the additional polymer in the total polymer content. However, it is submitted that an optimum polymer mass content is desirable and can be optimized through routine experimentation (MPEP 2144.05 II A). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the polymer mass content percent through routine experimentation.

**As to claim 10**, Koros (US 5599380) does not expressly teach a concentration of the first and second polymer solutions. However, it is submitted that an optimum polymer solution concentration is desirable and can be optimized through routine experimentation (MPEP 2144.05 II A). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the polymer solution concentrations and can be optimized through routine experimentation.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following patents are cited to show the state of art with respect to blood and tissue compatible polymers:

Brenner et al. (US 4973320) (col. 3, lines 9-12; polyurethane = tissue compatible polymer)

Meyst et al. (US 4283289) (col. 4, lines 28-30; polyamide = blood compatible polymer)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith J. Godfrey whose telephone number is 571-272-6391. The examiner can normally be reached on 8:00-5:00 Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina A. Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
CHRISTINA JOHNSON  
SUPERVISORY PATENT EXAMINER

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